REMARKS

The Office Action dated August 5, 2009, has been carefully reviewed and the following comments are made in response thereto. In view of the amendments and the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Applicants have added have added new claims directed to the specific substances recited in claims 25, 26, and 28. No new matter has been added.

The Rejection under 35 U.S.C. 112, first paragraph, should be withdrawn

Claims 25, 26, and 28 were rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. The crux of the rejection is that allegedly the specification does not provide adequate written description for the claimed genus. Applicants respectfully disagree. Contrary to the allegations in the Office Action, the specification clearly provides written description for anti-human CXCR4 antibodies and anti-human SDF-1 antibodies that function (a) to inhibit the binding between the ligand human SDF-1 and the receptor human CXCR4 and (b) to treat a solid tumor, to treat a disease pathologically caused by neovascularization or suppress vascularization as claimed.

I. Prior to discussing the merits of the rejection, Applicants note that the Examiner previously held the pending claims to be in compliance with the written description requirement. In the Office Action mailed February 27, 2007, the claims were rejected for allegedly failing to comply with the written description requirement. To address this rejection and in response to the Office Action, Applicants amended claims 25, 26, and 28 to read as currently pending. Subsequently, the Office indicated that all other rejections, which included the lack of written description rejection, recited in the Office Action mailed February 27, 2007 were withdrawn (*see* page 5 of the Office Action dated January 29, 2008). Thus, the Office previously indicated the pending claims to be in compliance with the written description requirement but now alleges they no longer comply with the written description requirement. Since the claims were previously indicated to be in compliance with the written description requirement and the claims were not amended since then, the claims continue to be in compliance with the written description requirement. Accordingly the rejection should be withdrawn on this ground alone.

II. *In re Alonso* is inapplicable to the instant situation and therefore cannot be relied upon to allege that the pending claims lack written description. The problem faced in *In re Alonso* was that the antigen

was not specified in sufficient detail; it was undefined. If the antigen is specified in sufficient detail, such as in the pending claims, it provides adequate written description for an antibody against the antigen. *See Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2003).

Alonso only discloses a hybridoma secreting monoclonal antibodies against a tumor from a single patient (*see In re Alonso*, p. 3). The specification of Alonso's application does not characterize the antigen to which the monoclonal antibodies must bind; it discloses only the molecular weight of the antigen (a 221 kD tumor surface antigen) in an Example (*see In re Alonso,* pp. 3, 9). Furthermore, the antibody was described in terms of being idiotypic to the neurofibrosarcoma of said human (*see In re Alonso*, p. 9). In other words, *In re Alonso* dealt with an undefined antigen. Alonso's claim to a broad genus of antibodies was held to lack sufficient written description because the application only disclosed an undefined antigen.

In contrast, in the instant application, the antigen is specified (*i.e.* human CXCR4 and human SDF-1). The specification clearly discloses the antigen including the amino acid sequence (*see* SEQ ID NO: 1 (human CXCR4); SEQ ID NO: 5, 9 (human SDF-1)). Contrary to the allegations in the Office Action implying that at the time of the invention 12G5 was the only known antibody against CXCR4 (*see* page 4 of the Office Action), at the time of the invention, numerous antibodies against (1) CXCR-4 (*see e.g.*, Delezay *et al.* (a copy of the Abstract of which is attached); Förster *et al.* (copy of which is attached) and (2) SDF-1 (Imai *et al.* (a copy of which is attached)) were known, some of which were even commercially available. At the time of the invention, it was also well-known that antibodies can readily be made against a known antigen. Accordingly, the claims have adequate written description and therefore the rejection should be withdrawn.

III. As the Examiner is aware and as previously noted by the Applicants, "as long as an applicant has a '*fully characterized* antigen' by its structure, formula, chemical name, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2003). As previously noted by the Examiner, the specification discloses the amino acid and nucleotides sequences of human CXCR4 (SEQ ID NO: 1) (page 14, lines 24 to 26) and human SDF-1 (SED ID NO: 5, 9) (page 15, lines 1 to 20). Furthermore, the specification discloses:

i. that both SDF-1 and CXCR4 are necessary for neovascularization (page 2, line 20 to page 4, line 10);
ii. known structural of details of CXCR4 (page 2, line 20 to page 4, line 10);
iii. the role of SDF-1 (page 2, line 20 to page 4, line 10);
iv. anti-SDF-1 antibodies (page 17, lines 13 to 20) and anti-CXCR4 antibodies (page 18, lines 10 to 11);

v. how to make such anti-SDF-1 and anti-CXCR4 antibodies (page 26, line 25 to page 32, line 36); and
vi. methods of treating cancer, treating a pathology caused by neovascularization, and suppressing vascularization with such antibodies (*see* page 38, lines 15 to 25).

Accordingly, each element of the claims is disclosed in the specification and one of skill in the art would recognize what is claimed in sufficient detail to reasonably conclude that the inventors were in possession of the claimed invention (*see* MPEP 2163).

The new arguments raised in the Office Action do not change the fact that the pending claims clearly comply with the written description requirement. The specification adequately describes anti-SDF-1 and anti-CXCR4 antibodies used in the methods and adequately describes the methods such that the skilled artisan would have considered Applicants in possession of the claimed invention.

To satisfy the written description requirement, an inventor is not required to describe every detail of his invention because disclosure obligations vary according to the art to which the invention pertains (MPEP 2163). Thus, the disclosure of an antigen is sufficient to satisfy the written description requirement for an antibody against the antigen and no specific examples of the antibody are required. *See Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004).

As described above, at the time of the invention, those of skill in the art would have known how to make antibodies against a known antigen (such as *e.g.* CXCR4 and SDF-1). If a receptor and its ligand are known, one of skill in the art can select an antibody having neutralizing activity well-known methods, such as *e.g.* by detecting the binding between the receptor and its ligand, without undue experimentation. Furthermore, at the time of invention, it was known that is possible to obtain neutralizing antibodies against CXCR4 and SDF-1.

The specification also adequately describes the claimed methods of the invention such that a skilled artisan would have considered the Applicants to be in possession of the claimed invention. In particular, the specification discloses the claimed methods and diseases (*see* page 38, lines 14 to 36 of the specification) and includes experimental evidence demonstrating Applicants' possession of the claimed invention (*see* page 48, lines 4 to 8; page 50, lines 14 to 29; page 52, line 19 to page 60, line 10 of the specification).

Thus, given the disclosure of the specification, those of skill in the art would clearly recognize that the inventors were in possession of the claimed invention and that therefore the claims comply with the written description requirements.

Accordingly, Applicants request withdrawal of the lack of written description rejection.

Conclusion

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
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